IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** **ETHICON WAVE 3 CASES LISTED IN PLAINTIFFS' EXHIBIT A**	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

ETHICON'S MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE CERTAIN OPINIONS AND TESTIMONY OF JOSEPH CARBONE, M.D.

In Wave 3 of this litigation, Plaintiffs adopt the *Daubert* motion they filed in relation to the general-causation opinions of Joseph Carbone, M.D., in Wave 1, Dkt. 2025. *See* Pls.' Notice of Adoption (Dkt. 2761). The Court has ruled on that Wave 1 motion. *See In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4958312 (S.D.W. Va. Aug. 25, 2016). Defendants Ethicon, Inc., Johnson & Johnson and, where applicable, Ethicon LLC (Ethicon) respectfully request that this Court again deny Plaintiffs' motion for the reasons expressed below and in accordance with this Court's August 25, 2016 Memorandum Opinion and Order.

ARGUMENTS AND AUTHORITIES

I. Any Nondisclosure of Dr. Carbone's Personal Complication Rate Was Substantially Justified and Harmless.

After questioning by Plaintiffs' counsel at deposition about his personal complication rates, Dr. Carbone disclosed that his complications rate is slightly lower than the rates reported in the medical literature. Ex. 1, Carbone 3/16/16 TVT Dep. Tr. 69:20-70:22; Ex. 2, Carbone 3/17/16 TVT Dep. Tr. 110:10-112:7. In his reports, Dr. Carbone had extensively discussed the complication rates published in the medical literature (Ex. B to Pls.' Mot. (Dkt. 2025-2),

Carbone TVT Report at 15-20; Ex. C to Pls.' Mot. (Dkt. 2025-3), Carbone Prolift Report at 10-25), and also relied on such rates and his clinical experience in forming his opinions on the safety and efficacy of Ethicon's mesh devices (Ex. 2, Carbone 3/17/16 TVT Dep. Tr. 121:1-13, 124:6-125:6, 128:2-19; Ex. 1 to Defs.' Opp'n (Dkt. 2180-1), Carbone Reliance List). Dr. Carbone did not, however, specifically discuss his personal complication rates in his report. *See In re: Ethicon, Inc.*, 2016 WL 4958312, at *3.

Dr. Carbone's personal-rate testimony is admissible because any nondisclosure was substantially justified and harmless. The Fourth Circuit applies a five-factor test to determine whether nondisclosure was substantially justified or harmless: "(1) the surprise to the party against whom the witness was to have testified; (2) the ability of the party to cure that surprise; (3) the extent to which allowing the testimony would disrupt the trial; (4) the explanation for the party's failure to name the witness before trial; and (5) the importance of the testimony." *Eghnayem v. Boston Scientific Corp.*, 57 F. Supp. 3d 658, 718 (S.D.W. Va. 2014) (quoting *Hoyle v. Freightliner, LLC*, 650 F.3d 321, 329-30 (4th Cir. 2011)).

First, there was no "surprise" to Plaintiffs because Dr. Carbone's reports provided reasonable notice to Plaintiffs of his safety and efficacy opinions based on the complication rates reported in the medical literature, as well as his personal experience. Ex. B to Pls.' Mot. (Dkt. 2025-2), Carbone TVT Report at 1-3, 15-20, 23-25; Ex. C to Pls.' Mot. (Dkt. 2025-3), Carbone Prolift Report at 1-3, 10-25, 28-36. Dr. Carbone's personal-rate testimony was merely an elaboration of the disclosed opinions, not a new opinion.

Regarding the second *Hoyle* factor, there was no surprise to cure and, even if there was, Plaintiffs were able to question Dr. Carbone about his complication rates at deposition. Indeed, it was Plaintiffs who opened the door to Dr. Carbone's personal-rate testimony with their counsel's questioning in the first instance. Ex. 1, Carbone 3/16/16 TVT Dep. Tr. 69:20-70:22.

The third *Hoyle* factor is not implicated as trial has not started. *See, e.g.*, *Eghnayem*, 57 F. Supp. 3d at 718. And as to the fourth factor, any nondisclosure was unintentional as evidenced by the consistency between Dr. Carbone's complication rate and the rates reported in the literature which were discussed in his reports. Finally, because Dr. Carbone's personal-rate testimony was simply confirmation of his overall opinion on the safety and efficacy of TVT and Prolift, any nondisclosure of this testimony was harmless.

At bottom, any nondisclosure of Dr. Carbone's personal complication rate was substantially justified and harmless, and this testimony is admissible.[1]

II. Dr. Carbone Is Entitled to Testify About the Risks of Implanting Mesh and Whether They Appeared in the IFUs, and the Common Knowledge of Physicians Regarding Risks.

Dr. Carbone's proposed testimony is consistent with this Court's orders. This Court has determined that Dr. Carbone is qualified to testify "about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU." *In re: Ethicon, Inc.*, 2016 WL 4958312, at *3. Further, the Court has expressed no opinion about expert testimony regarding "whether certain risks were common knowledge in the medical community," and therefore has not precluded this expert testimony. *See, e.g., In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4582231, at *3 n.2 (S.D.W. Va. Sept. 1, 2016) ("The plaintiffs' Motion focuses on whether Dr. Woods is qualified to offer expert testimony about what should be included in or what may be excluded from an IFU. So I offer no opinion on whether Dr. Woods may testify about whether certain risks were common knowledge."); *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4557036, at *3 n.2 (S.D.W. Va.

[1] To the extent Plaintiffs challenge Dr. Carbone's qualifications and methodology regarding his personal-complications opinion, Ethicon incorporates and adopts its Opposition to Plaintiffs' Wave 1 motion (Dkt. 2180) at 2-5.

Aug. 31, 2016) (same, with respect to Dr. Drolet); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4536875, at *4 n.2 (S.D.W. Va. Aug. 30, 2016) (same, with respect to Dr. Serels); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4542054, at *3 n.2 (S.D.W. Va. Aug. 30, 2016) (same, with respect to Dr. Elser); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4536872, at *3 n.2 (S.D.W. Va. Aug. 30, 2016) (same, with respect to Dr. Sepulveda-Toro); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4493666, at *4 n.2 (S.D.W. Va. Aug. 25, 2016) (same, with respect to Dr. Toglia); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4493681, at *3 n.2 (S.D.W. Va. Aug. 25, 2016) (same, with respect to Dr. Pramudji).

Dr. Carbone is qualified to testify regarding risks that are within the common knowledge of surgeons who perform pelvic surgeries. As detailed in Ethicon's Wave 1 Opposition, Dr. Carbone has extensive clinical experience with suburethral mesh-sling procedures, prolapse reconstructions with nonmesh and mesh techniques, and mesh repairs. Defs.' Opp'n (Dkt. 2180) at 3. He has kept current with the relevant medical literature on the use of mesh since 1998 when he was first introduced to mesh. Ex. 1, Carbone 3/16/16 TVT Dep. Tr. 26:17-24. Because of his specialized knowledge and experience, Dr. Carbone has trained and educated hundreds of surgeons in the treatment of incontinence and prolapse surgeries using various mesh slings and devices. Ex. B to Pls.' Mot. (Dkt. 2025-2), Carbone TVT Report at 2-3; Ex. C to Pls.' Mot. (Dkt. 2025-3), Carbone Prolift Report at 2-3. In addition, Dr. Carbone relies on his review of complications reported in the medical literature, statements of leading medical societies, discussions with other surgeons, and general knowledge as a pelvic-floor surgeon in reaching his opinions. Ex. 2, Carbone 3/17/16 TVT Dep. Tr. 63:3-9, 113:21-114:23, 121:1-13, 128:21-129:22.

As a practicing surgeon who went through years of medical training, has extensive clinical experience with pelvic floor surgeries, teaches other physicians about these surgeries, and keeps up with the medical literature, Dr. Carbone is uniquely qualified to offer opinions about what is within the common knowledge of physicians who perform pelvic floor surgeries. Indeed, only a physician with such training and experience *could* testify as to common knowledge of surgeons who perform pelvic surgeries.

Because Dr. Carbone has the qualifications and requisite foundation, he may offer his opinion that exposure/erosion is the only risk unique to mesh devices, and that pain, dyspareunia, infection, urinary problems, recurrent incontinence, bleeding, organ perforation, neuro-muscular problems, scarring, mesh contraction, roping, curling, degradation, and cytotoxicity are ***not*** risks associated with mesh devices. Ex. B to Pls.' Mot. (Dkt. 2025-2), Carbone TVT Report at 20; Ex. C to Pls.' Mot. (Dkt. 2025-3), Carbone Prolift Report at 18-25, 28-29; Ex. 1, Carbone 3/16/16 TVT Dep. Tr. 106:4-107:18; Ex. 2, Carbone 3/17/16 TVT Dep. Tr. 112:20-113:11. In addition, Dr. Carbone is qualified to testify that those risks are generalized risks of mesh surgery and within the common knowledge of surgeons who perform pelvic surgeries, including mesh implantations. Ex. B to Pls.' Mot. (Dkt. 2025-2), Carbone TVT Report at 20; Ex. C to Pls.' Mot. (Dkt. 2025-3), Carbone Prolift Report at 18-25, 28-29; Ex. 1, Carbone 3/16/16 TVT Dep. Tr. 106:4-107:18; Ex. 2, Carbone 3/17/16 TVT Dep. Tr. 112:20-113:11, 113:13-19.[2]

[2] Moreover, this testimony will be helpful to juries assessing warning adequacy because a manufacturer has no duty to warn of risks commonly known to the surgeons who use the device. As stated generally in the Restatement (Third) of Torts: Products Liability § 2 cmt. j, a product seller "is not subject to liability for failing to warn or instruct regarding risks and risk-avoidance measures that should be obvious to, or generally known by, foreseeable product users." *See also* RESTATEMENT (SECOND) OF THE LAW OF TORTS §§ 388(b), 402A cmt. j. In fact, the FDA has said that information may be omitted from labeling "if, but only if, the article is a device for which directions, hazards, warnings and other information are *commonly known* to practitioners licensed by law to use the device." 21 C.F.R. § 801.109(c) (emphasis added).

Thus, Ethicon respectfully requests that this Court deny Plaintiffs' motion to the extent it seeks to exclude Dr. Carbone's testimony regarding the common knowledge of physicians regarding risks associated with pelvic floor surgery, and risks of implanting mesh and whether they were included in the IFUs.

III. Plaintiffs' Motion to Exclude Dr. Carbone's "Design Opinions" Should Be Denied as Moot.

Plaintiffs assert the identical arguments and record regarding Dr. Carbone's "design opinions" that they asserted in Wave 1.[3] This Court has already denied Plaintiffs' challenge to Dr. Carbone's "design opinions" because Dr. Carbone "has not expressed any opinions about the process of designing a product." *In re: Ethicon, Inc.*, 2016 WL 4958312, at *3-4. Ethicon respectfully requests that this Court rule in the same manner in the Wave 3 cases and again deny as moot Plaintiffs' motion with respect to Dr. Carbone's "design opinions."

CONCLUSION

For the foregoing reasons, Ethicon respectfully requests that Plaintiffs' motion be denied in its entirety.

Respectfully submitted,

ETHICON, INC. AND
JOHNSON & JOHNSON

/s/ *Rita A. Maimbourg*
Rita A. Maimbourg
TUCKER ELLIS LLP
950 Main Avenue, Suite 1100
Cleveland, OH 44113-7213
Telephone: 216.592.5000
Facsimile: 216.592.5002
rita.maimbourg@tuckerellis.com

[3] To the extent Plaintiffs challenge Dr. Carbone's qualifications and methodology regarding his testimony on the *safety and efficacy* of the TVT and Prolift designs, Ethicon incorporates and adopts its Opposition to Plaintiffs' Wave 1 motion (Dkt. 2180) at 8-11.

/s/ David B. Thomas
David B. Thomas (W.Va. Bar #3731)
THOMAS COMBS & SPANN PLLC
300 Summers St.
Suite 1380 (25301)
P.O. Box 3824
Charleston, WV 25338
Telephone: 304.414.1807
dthomas@tcspllc.com

/s/ Christy D. Jones
Christy D. Jones
BUTLER SNOW LLP
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010
Telephone: 601.985.4523
christy.jones@butlersnow.com

CERTIFICATE OF SERVICE

I certify that on October 10, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ *Rita A. Maimbourg*
Rita A. Maimbourg
TUCKER ELLIS LLP
950 Main Avenue, Suite 1100
Cleveland, OH 44113-7213
Telephone: 216.592.5000
Facsimile: 216.592.5002
rita.maimbourg@tuckerellis.com